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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,272	08/13/2001	Christoph Kirsch	9730-001	3234

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AKERMAN SENTERFITT
P.O. BOX 3188
WEST PALM BEACH, FL 33402-3188

EXAMINER	
MARVICH, MARIA	
ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
12/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/831,272	KIRSCH ET AL.	
	Examiner	Art Unit	
	MARIA B. MARVICH	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,8,9,22,39,42-47 and 49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,8,9,39 and 44-47* is/are rejected.

7)☒ Claim(s) *2,3,22,39,42,43,46,47 and 49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/28/08 has been entered.

Claims 2, 3, 8, 9, 22, 39, 42-47 and 49 are pending and under examination.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). The address for Kirsh has been altered with out initials.

Claim Objections

Claims 2, 3, 22, 39, 42, 46, 47 and 49 are objected to because of the following informalities: the claims have been found to have several informalities in clarity or concise antecedent basis for which amendments are recommended below. For example, the recitation in the preamble that the promoter is "capable of local gene expression" requires recitation -of an operably linked nucleic acid sequence-- followed by amendment in the body of the claim to --

expression of the nucleic acid sequence--. As well, the references throughout the claims to pathogen infection, pathogen elicitor treatment or both are not consistently referenced and should be amended to indicate the same terms throughout. Finally, the recitation "comprising" due to the lengthy preamble loses significance and should be amended to --the promoter comprising-- or --the method comprising--.

The following amendments are recommended solely to address the informalities of the claims.

Claim 2. (Currently Amended) A chimeric promoter capable of local gene expression in plants of an operably linked nucleic acid sequence, wherein the expression is induced by a pathogen elicitor treatment, a pathogen infection, or both, ~~comprising~~ wherein the promoter comprises: (i) two or more cis-acting elements sufficient to direct[[:]] the pathogen-elicitor-~~specific~~ induced expression of [[a]] the nucleic acid sequence, the pathogen-infection-~~specific~~ induced expression of a nucleic acid sequence, or both, wherein at least one of said two or more cis-acting elements consists of the nucleotide sequence of SEQ ID NO: 11, and (ii) a minimal promoter, wherein induction of said local gene expression upon the pathogen elicitor treatment and/or the pathogen infection is between 10-fold and 15-fold.

Claim 3. (Currently Amended) A chimeric promoter capable of local gene expression in plants of an operably linked nucleic acid sequence, wherein the expression is induced by a pathogen elicitor treatment, a pathogen infection, or both, ~~comprising~~ wherein the promoter comprises: (i) two or more cis-acting elements sufficient to direct[[:]] the pathogen-elicitor-~~specific~~ induced expression of [[a]] the nucleic acid sequence,, the pathogen-infection-~~specific~~

induced expression of [[a]] the nucleic acid sequence, or both, wherein at least one of said two or more cis-acting elements consists of the nucleotide sequence of SEQ ID NO: 11, and (ii) a minimal promoter, further comprising a cis-acting element having the nucleotide sequence selected from the group consisting of: SEQ ID NO:1 and SEQ ID NO:2.

Claim 22. (Currently Amended) An isolated cis-acting element sufficient to direct pathogen-elicitor-specific expression, pathogen-infection-specific expression, or both, of an operably linked nucleic acid, wherein the element consists ~~consisting~~ of the nucleotide sequence of SEQ ID NO: 11.

Claim 39. (Currently Amended) A promoter obtainable by a method of rendering a gene responsive to pathogens, wherein the method comprises ~~comprising~~ inserting at least one cis-acting element sufficient to direct pathogen-elicitor-~~specific~~ induced expression, pathogen-infection-~~specific~~ induced expression, or both, of an operably linked nucleic acid, into the promoter of said gene, wherein (1) induction of local gene expression in plants upon the pathogen elicitor treatment, the pathogen infection, or both, is between 10-fold and 15-fold and wherein the at least one *cis*-element comprises SEQ ID NO: 11, or (2) induction of local gene expression in plants upon the pathogen elicitor treatment, the pathogen infection, or both is at least 15-fold and the at least one cis-acting element comprises two copies of SEQ ID NO: 11, or a combination of one copy of SEQ ID NO: 11 and one copy of SEQ ID NO: 7.

Claim 42. (Currently Amended) A chimeric promoter capable of local gene expression in plants of an operably linked nucleic acid sequence, wherein the expression is induced by a pathogen elicitor treatment, a pathogen infection, or both, ~~comprising~~ wherein the promoter comprises: (i) two or more cis-acting elements sufficient to direct[[:]] the pathogen-elicitor-~~specific~~ induced expression of [[a]] the nucleic acid sequence, the pathogen-infection-~~specific~~ induced expression of [[a]] the nucleic acid sequence, or both, wherein the two or more *cis*-acting elements comprise at least one copy of the nucleotide sequence of SEQ ID NO: 11, and at least one copy of the nucleotide sequence of SEQ ID NO:7, and (ii) a minimal promoter.

46. (Currently Amended) A method for the production of transgenic plants, transgenic plant cells or transgenic plant tissues, wherein the method comprises ~~comprising~~ introducing a chimeric promoter according to claim 2, 3, 8, 9, 39, 42, 43, 47 or 49, into the genome of ~~said plant, plant cell or plant tissue~~ plants, plant cells or plant tissues to produce the transgenic plants, the transgenic plants cells and or the transgenic plant tissues.

Claim 47. (Currently Amended) A chimeric promoter capable of local gene expression in plants[[,]] of an operably linked nucleic acid sequence, wherein the expression is induced by a pathogen elicitor treatment, a pathogen infection, or both, ~~comprising~~ wherein the promoter comprises: (i) two or more cis-acting elements sufficient to direct[[:]] the pathogen-elicitor-~~specific~~ induced expression of [[a]] the nucleic acid sequence, the pathogen-infection-~~specific~~ induced expression of [[a]] the nucleic acid sequence, or both, (ii) a minimal promoter, wherein induction of said local gene expression upon the pathogen elicitor treatment and/or the pathogen

infection is at least 15-fold, ~~the chimeric promoter~~ the two or more cis-acting elements comprising: two copies of SEQ ID NO:11, or the combination of one copy of SEQ ID NO:11 followed by one copy of SEQ ID NO:7, or the combination of four copies of SEQ ID NO:11 followed by four copies of SEQ ID NO:7.

Claim 49. (Currently Amended) A chimeric promoter capable of local gene expression in plants[[,]] of an operably linked nucleic acid sequence, wherein the expression is induced by a pathogen elicitor treatment, ~~upon~~ a pathogen infection, or both, ~~comprising~~ wherein the promoter comprises: (i) two or more cis-acting elements sufficient to direct[[:]] the pathogen-elicitor-~~specific~~ induced expression of [[a]] the nucleic acid sequence, the pathogen-infection-~~specific~~ induced expression of [[a]] the nucleic acid sequence, or both, wherein at least one of said two or more cis-acting elements consists of the nucleotide sequence of SEQ ID NO: 11, and (ii) a minimal promoter, further comprising a cis-acting element having the nucleotide sequence selected from the group consisting of: SEQ ID NO:3 and SEQ ID NO:4.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 8, 9, 39 and 44-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 1) a chimeric promoter capable of mediating local gene expression in plants upon pathogen infection or pathogen elicitor treatment and induction is

between 10 and 15 fold wherein the promoter comprises 4 copies of SEQ ID NO:11 followed by 4 copies of SEQ ID NO:7, consists of SEQ ID NO:11, comprises 4 copies of SEQ ID NO:11, comprises one copy or 4 copies of SEQ ID NO:11 followed respectively by one copy or 4 copies of SEQ ID NO:3 or 4 or 2) a chimeric promoter capable of mediating local gene expression in plants upon pathogen infection and induction is between 15 and 81 fold wherein the promoter comprises either two copies of SEQ ID NO:11 or one copy of SEQ ID NO:11 followed by one copy of SEQ ID NO:7 or 4 copies of SEQ ID NO:11 followed by four copies of SEQ ID NO:7 or two copies of SEQ ID NO:3 or 4 followed by two copies of SEQ ID NO:11 or two copies of SEQ ID NO:1 followed by two copies of SEQ ID NO:11, does not reasonably provide enablement for any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. **This is a new rejection.**

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation (*United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is required is not based on a single factor but is rather a conclusion reached by weighing many factors (See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter, 1986) and In *re Wands*, 8USPQ2d 1400 (Fed. Cir. 1988); these factors include the following:

The instant claims are drawn to a chimeric promoter that is capable of directing elicitor-specific expression of a nucleic acid. The chimeric promoters are recited as inducing expression upon elicitor treatment of pathogen infection or pathogen elicitor treatment of 10-15 or greater

than 15 fold. The specification teaches the identification of 7 elements that are capable of elicitor responsive expression alone or in combination with one another. The instant claims are directed to chimeric promoters that are constructed using SEQ ID NO:11 or element D. The specification teaches that the following combinations with SEQ ID NO:11 have been tested and provide the fold induction mediated by these promoters of expression in plants. Induction is less than 10 fold when the elements are 4 copies of SEQ ID NO:3 or 4 followed by 4 copies of SEQ ID NO:11, induction is between 10 and 15 fold wherein the promoter comprises 4 copies of SEQ ID NO:11 followed by 4 copies of SEQ ID NO:7, consists of SEQ ID NO:11, comprises 4 copies of SEQ ID NO:11, comprises one copy or 4 copies of SEQ ID NO:11 followed respectively by one copy or 4 copies of SEQ ID NO:3 or 4 or 2) a chimeric promoter capable of mediating local gene expression in plants upon pathogen infection and induction is between 15 and 81 fold wherein the promoter comprises either two copies of SEQ ID NO:11 or one copy of SEQ ID NO:11 followed by one copy of SEQ ID NO:7 or 4 copies of SEQ ID NO:11 followed by four copies of SEQ ID NO:7 or two copies of SEQ ID NO:3 or 4 followed by two copies of SEQ ID NO:11 or two copies of SEQ ID NO:1 followed by two copies of SEQ ID NO:11. Hence, it is clear that the combinations could not be predicted. Rather, the actual combination of elements to provide specific inductive levels does not really meet a pattern. For example 4 copies of SEQ ID NO:7 followed by 4 copies of SEQ ID NO:11 provide induction to 10 fold, however, 4 copies of SEQ ID NO:11 followed by 4 copies of SEQ ID NO:7 provide induction up to 30 fold. The specification states that the difference in levels is due to steric hindrance (see page 37). Further confusing the issue is that two copies of SEQ ID NO:7 followed by 2 copies of SEQ ID NO:11 induce to 81 fold. Hence, the patterns of induction are not predictable and must be empirically

determined. As well, the recitation of greater then 15 fold has no upper limit whereas the results suggest that in fact there is an upper limit.

This exacerbates the unpredictability of determining which embodiments are productive as the claims broadly recite components of the promoter. For example, claim 2 recites that expression is between 10-15 fold whereas the promoter comprises two or more cis-acting elements wherein at least one of the elements consists of SEQ ID NO:11. A promoter comprising one copy of SEQ ID NO:11 can ha e innumerable elements associated with only a fraction of which have been tested. However, when looking to the assessed combinations, it is clear that not all have inductive levels of 10-15 fold and furthermore, considering all the combinations that are possible aside form the disclosed combinations provides a large genus of promoters wherein the ability to predict function is uncertain.

Given the lack of guidance in the specification, the large and diverse group of chimeric promoters recited and the highly unpredictable nature of the ability to predict components to produce a promoter with specific induction levels, it is concluded that a person of skill in the art would have had to conduct undue experimentation in order to practice the claimed

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD
Primary Examiner
Art Unit 1633

/Maria B Marvich/
Primary Examiner, Art Unit 1633